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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/016,159	01/30/1998	JONG Y. LEE	07004-002004	6621

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HUGH MCTAVISH
MCTAVISH PATENT FIRM
429 BIRCHWOOD COURTS
BIRCHWOOD, MN 55110

EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/016,159

Applicant(s)

LEE, JONG Y.

Examiner

Fozia M. Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5,10,11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

1a. Receipt of Applicants' amendment and arguments, filed on 01 December 2004 and 2004 and 7 March 2005 are acknowledged. Claims 3, 5, 10, 11 and 13 are pending, of which claim 10 stands withdrawn, since it is drawn to non-elected invention. Claims 3, 5, 11 and 13 are under consideration.

1b. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 01 December 2004.

(I) The rejection of claims 3, 5, 11 and 13 made under 35 U.S.C. 112, first, for not complying with the written description requirement. The recitation of SEQ ID Nos: obviates this rejection.

Sequence:

2a. Applicants submitted a paper copy of the sequence listing as well as CRF. Thus, this case now complies with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

New Objections and Rejections necessitated by Applicant's Amendment:

Specification:

2b. The specification is objected to under 35 U.S.C. 132(a), because the amendment filed **07 March 2005** introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants

filed new sequence listing which contains seven SEQ ID Nos: 1-7. However, the instant application as originally filed on **01/30/1998** contained only 4 sequences, SEQ ID Nos: 1-4. As originally filed SEQ ID NO: 1 comprised 23 base pairs, SEQ ID NO:2, comprised 22 base pairs, SEQ ID NO:3 comprised 18 base pairs and SEQ ID NO:4 comprised both 1527 base pairs and 518 amino acid residues.

Applicant filed sequence listing six times in the instant application and this makes the examination of this case very difficult.

In addition to the original sequence listing filed on 01/30/1998, Applicant filed new set of sequences on **01/19/1999**. This sequence listing comprised of 5 sequences and 5 SEQ ID Nos.; SEQ ID Nos:1-3 were the same as the originally filed sequences, however originally filed SEQ ID NO:4 was broken into two SEQ ID Nos, SEQ ID NO:4, which comprised 1527 base pairs and SEQ ID NO:5 which comprised 508 amino acid residues. The sequences filed on 19 January 1999 introduced new matter, because new SEQ ID NO:5 differed from the protein represented by original SEQ ID NO:4. Original SEQ ID NO:4 contained 518 amino acid residues while new SEQ ID NO:5 contained 508 amino acid residues. Furthermore, new SEQ ID NO:5 differed from original SEQ ID NO:5 at positions 102, 189, 190, 221, 244 and 483. These changes were not in the instant specification as originally filed. Accordingly, these changes were rejected as introducing new matter into the disclosure in the office actions mailed on 09/26/2000 and 07/13/2001. Although an amendment filed on 01/19/1999 removed new matter from the claims, it did not address the new matter introduced into the

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specification through the sequence listing. Therefore, this new matter was never dropped from the case.

Applicant filed yet another sequence listing on **07/07/2003**, which contained only four sequences, SEQ ID NO: 1 comprised 23 base pairs, SEQ ID NO:2, comprised 22 base pairs, SEQ ID NO:3 comprised 18 base pairs and SEQ ID NO:4 comprised 1527 base pairs. Applicant again filed new sequence listing on **06/18/2004**. This new listing contained 4 sequences. SEQ ID NO:1 contained 508 amino acids, SEQ ID NO:2 contained 1527 bases, SEQ ID NO:3 contained 508 amino acids, SEQ ID NO:4 contained 1527 base. This sequence listing omitted original SEQ ID Nos:1, 2 and 3 and used these sequence identifiers for completely disparate sequences. Applicant filed yet new sequence listing on **12/01/04**, which reintroduced the first 3 originally filed sequences. Thus, this last sequence listing consists of 7 sequences. Finally Applicant filed new listing on **03/07/05**, which also contains 7 sequences. The filing of all these sequences not only introduces confusion but also introduces new matter into the disclosure. The only sequences that have support in the specification as originally filed are the sequences filed on **01/30/1998**. The Examiner agreed to let Applicant recite SEQ ID Nos in the claims, however, at the time the understanding was that there was only one SEQ ID NO: for the human EPO receptor amino acid sequence, the one represented by SEQ ID NO:4. Applicant originally filed only one amino acid sequence for the human EPO receptor, said sequence is now described by Applicant as being disclosed by Jones.

Accordingly, only original SEQ ID Nos: 1, 2, 3, 4, and 5 (SEQ ID NO:5 is from the protein recited in original SEQ ID NO:4), which was filed on **01/30/1998** is supported by the application. All of the other sequences introduce new matter and must be removed by the Applicant in the next response.

Applicant is required to cancel the new matter in the reply to this Office Action. Moreover, Applicant is required to clarify the confusion that exists regarding the numerous sequence listing in the instant case.

Claim Rejections - 35 U.S.C. § 112:

3a. Claims 3, 5, 11 and 13 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention.

The recitation of SEQ ID Nos: 5, 7, 4 and 6 in the claims introduces new matter, into the claims. As set forth in section 2b of this office action, the specification as originally filed disclosed only 4 sequences: SEQ ID NO: 1 comprised 23 base pairs, SEQ ID NO:2, comprised 22 base pairs, SEQ ID NO:3 comprised 18 base pairs and SEQ ID NO:4 comprised both 1527 base pairs and 518 amino acid residues. The original specification disclosed only one nucleic acid encoding the human EPO receptor, said nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:4 and only one amino acid sequence for the human EPO receptor, also comprising SEQ ID NO:4. The amino acid sequence originally disclosed in the instant specification comprised 518

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amino acid residues. Accordingly, the recitation of SEQ ID Nos: 5, 7, 4 and 6 introduces new matter into the claims. The specification as originally filed disclosed only 4 sequences (SEQ ID NO:4 was an identifier for both nucleotide sequence and the encoded polypeptide), thus, only the originally filed amino acid and nucleotide sequences meet the written description provision of 35 U.S.C. 112, first paragraph.

Therefore, only the isolated polypeptide and the isolated nucleic acid comprising the sequences originally filed on 01/30/1998, meet the written description provision of 35 U.S.C. §112, first paragraph. Reciting the appropriate SEQ ID: NOs in the claims would obviate this rejection.

4. Claims 3, 5, 11, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 3 and 11 recite the phrase "..... about" which renders the claims indefinite because it is unclear whether the claimed polypeptide consists only of the amino acid residues 25-250 of full length human erythropoietin receptor, or about 30-249, etc. The metes and bounds of the claims cannot be ascertained. Appropriate correction is required.

Claims 5 and 11 are rejected insofar as they depend on claim 3 for the limitations set forth directly above.

Conclusion:

5. No claim is allowed.

Claims 3, 5, 11 and 13 are free of the prior art of record. The following is prior art made of record that is not relied upon, but is considered pertinent to applicant's disclosure.

I. The EPO receptor was cloned and expressed at the time the instant application was filed; Jones et al. Blood, Vol.76, No.1, July 1990. However, there was no disclosure of an isolated polypeptide that consists of only the extracellular domain, i.e amino acid residues 25-250, that was shown to bind to the erythropoietin molecule.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-

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0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
07 June 2005

PREMA MERTZ
PREMA MERTZ
PRIMARY EXAMINER